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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

VALEANT PHARMACEUTICALS NORTH AMERICA LLC; VALEANT PHARMACEUTICALS IRELAND LTD.; DOW PHARMACEUTICAL SCIENCES, INC.; and KAKEN PHARMACEUTICAL CO., LTD., Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD., Defendants.	Civil Action No. 19-00990 *Document Electronically Filed*

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Valeant Pharmaceuticals North America LLC ("Valeant"), Valeant Pharmaceuticals Ireland Ltd. ("Valeant Ireland"), Dow Pharmaceutical Sciences, Inc. ("Dow"), and Kaken Pharmaceutical Co., Ltd. ("Kaken") (collectively, "Plaintiffs") by way of this Complaint against Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") (collectively, "Teva") allege as follows:

THE PARTIES

1. Plaintiff Valeant is a limited liability company organized and existing under the laws of Delaware having its principal place of business at 400 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807.

2. Plaintiff Valeant Ireland is a company existing under the laws of Ireland having an office at 3013 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

3. Plaintiff Dow is a corporation organized and existing under the laws of Delaware having its principal place of business at 1330 Redwood Way, Petaluma, California 94954.

4. Plaintiff Kaken is a corporation organized and existing under the laws of Japan having its principal place of business at 20th Floor, Bunkyo Green Court, 28-8, Honkomagome 2-chome, Bunkyo-ku, Tokyo 113-8650, Japan.

5. Upon information and belief, Teva USA is a corporation organized and existing under the laws of Delaware, having a principal place of business at 425 Privet Road, Horsham, PA 19044.

6. Upon information and belief, Teva Ltd. is a corporation organized and existing under the laws of Israel, having its principal place of business at 5 Bazel, Petah Tikva, Israel, 004951033. Upon information and belief, Teva USA is a wholly-owned subsidiary of Teva Ltd.

NATURE OF THE ACTION

7. This is an action for infringement of United States Patent No. 10,105,444 ("the '444 patent") arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281. This action relates to Teva USA's filing of an Abbreviated New Drug Application ("ANDA") under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration

("FDA") approval to market its generic efinaconazole topical solution, 10% ("Teva's generic efinaconazole topical solution"). [1]

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), and 2201-02.

9. Upon information and belief, this Court has jurisdiction over Teva USA. Upon information and belief, Teva USA is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Teva USA directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Teva's generic efinaconazole topical solution. Upon information and belief, Teva USA purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Teva USA operates and maintains branches in Fairfield, New Jersey, Hackensack, New Jersey, and Parsippany-Troy Hills, New Jersey. Upon information and belief, Teva USA has received as much as $40 million in tax breaks to move its headquarters from Pennsylvania to Parsippany-Troy Hills, New Jersey. Upon information and belief, Teva USA has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

10. Teva USA has taken the costly, significant step of applying to the FDA for

[1] Plaintiffs previously brought an action for infringement of United States Patent Nos. 7,214,506 ("the '506 patent"), 8,039,494 ("the '494 patent"), 8,486,978 ("the '978 patent"), 9,302,009 ("the '009 patent"), 9,566,272 ("the '272 patent"), 9,662,394 ("the '394 patent"), 9,861,698 ("the '698 patent"), and 9,877,955 ("the '955 patent"). That action is currently pending in this Court as Case No. 3:18-cv-14209 (PGS) (LHG), and Plaintiffs hereby incorporate by reference their Complaint against Teva (ECF No. 1) in that action.

approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at, upon information and belief, the New Jersey and elsewhere. Teva USA's ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs. Upon information and belief, Teva USA intends to direct sales of its drugs into New Jersey, among other places, once it has the requested FDA approval to market them. Upon information and belief, Teva USA will engage in marketing of its proposed ANDA products in New Jersey upon approval of its ANDA.

11. Upon information and belief, this Court has jurisdiction over Teva Ltd. Upon information and belief, Teva Ltd. is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Teva Ltd. directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Teva's generic efinaconazole topical solution. Upon information and belief, Teva Ltd. purposefully has conducted and continues to conduct business in this judicial district, for example, through its subsidiary Teva USA. Upon information and belief, Teva Ltd. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

12. Teva knows or should know that Julia® is manufactured for Valeant Pharmaceuticals North America LLC in Bridgewater, NJ 08807 USA at least because that information is included in the label and prescribing information for Julia®.

13. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

14. Venue is proper against Teva USA because, *inter alia*, it maintains a regular and established place of business in this judicial district.

15. Venue is proper against Teva Ltd., a foreign corporation, in any judicial district that has personal jurisdiction, including this judicial district.

THE PATENT IN SUIT

16. The United States Patent and Trademark Office ("PTO") issued the '444 patent on October 23, 2018. The '444 patent claims, generally speaking, *inter alia*, pharmaceutical formulations including ethanol, cyclomethicone, diisopropyl adipate, C12-15 alkyl lactate and antioxidant. Plaintiffs hold all substantial rights in the '444 patent and have the right to sue for infringement thereof. The '444 patent is valid and enforceable. A copy of the '444 patent is attached hereto as Exhibit A.

17. Dow is the holder of New Drug Application ("NDA") No. 203567 for Jublia®, which the FDA approved on June 6, 2014. In conjunction with NDA No. 203567, the '444 patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

18. Efinaconazole topical solution, 10% is sold in the United States under the trademark Jublia®.

TEVA'S INFRINGING ANDA SUBMISSION

19. Upon information and belief, Teva USA filed or caused to be filed with the FDA ANDA No. 211827, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

20. Upon information and belief, Teva USA's ANDA No. 211827 seeks FDA approval to sell in the United States Teva's generic efinaconazole topical solution, intended to be a generic version of Jublia®.

21. Kaken and Dow received a letter dated December 5, 2018 from Teva purporting to be a Notice of Certification for ANDA No. 211827 ("Teva's notice letter") under 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c) that included a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

22. Teva USA's notice letter alleges that Teva USA has submitted to the FDA ANDA No. 211827 seeking FDA approval to sell Teva's generic efinaconazole topical solution, intended to be a generic version of Julia®.

23. Upon information and belief, ANDA No. 211827 seeks approval of Teva's generic efinaconazole topical solution that is the same, or substantially the same, as Julia®.

COUNT I AGAINST TEVA

Infringement of the '444 Patent under § 271(e)(2)

24. Paragraphs 1-23 are incorporated herein as set forth above.

25. Under 35 U.S.C. § 271(e)(2), Teva has infringed at least one claim of the '444 patent by submitting, or causing to be submitted to the FDA, ANDA No. 211827 seeking approval for the commercial marketing of Teva's generic efinaconazole topical solution before the expiration date of the '444 patent.

26. Upon information and belief, Teva's generic efinaconazole topical solution will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the '444 patent.

27. Upon information and belief, Teva will, through the manufacture, use, import, offer for sale, and/or sale of Teva's generic efinaconazole topical solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '444 patent.

28. If Teva's marketing and sale of its generic efinaconazole topical solution prior to

the expiration of the ’444 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT II AGAINST TEVA

Declaratory Judgment of Infringement of the ’444 Patent

29. Paragraphs 1-28 are incorporated herein as set forth above.

30. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

31. There is an actual case or controversy such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

32. Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Teva’s generic efinaconazole topical solution before the expiration date of the ’444 patent, including Teva’s filing of ANDA No. 211827.

33. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Teva’s generic efinaconazole topical solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’444 patent.

34. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Teva’s generic efinaconazole topical solution will constitute infringement of at least one claim of the ’444 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment in their favor and against Teva on the patent infringement claims set forth above and respectfully request

that this Court:

1. enter judgment that, under 35 U.S.C. § 271(e)(2), Teva has infringed at least one claim of the ’444 patent by submitting or causing to be submitted ANDA No. 211827 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Teva’s generic efinaconazole topical solution before the expiration of the ’444 patent;

2. order that that the effective date of any approval by the FDA of Teva’s generic efinaconazole topical solution be a date that is not earlier than the expiration of the ’444 patent, or such later date as the Court may determine;

3. enjoin Teva from the commercial manufacture, use, import, offer for sale, and/or sale of Teva’s generic efinaconazole topical solution until expiration of the ’444 patent, or such later date as the Court may determine;

4. enjoin Teva and all persons acting in concert with Teva from seeking, obtaining, or maintaining approval of Teva’s ANDA No. 211827 until expiration of the ’444 patent;

5. declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses, and disbursements in this action, including reasonable attorney’s fees;

6. award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: January 23, 2019
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

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CERTIFICATION OF NON-ARBITRABILITY PURSUANT TO LOCAL CIVIL RULE 201.1(d)

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks declaratory and injunctive relief and, therefore, is not subject to mandatory arbitration.

I certify under penalty of perjury that the foregoing is true and correct.

Dated: January 23, 2019
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

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